

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU2004/001485

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. 7: A61M 39/00, A61M 1/10		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
DWPI - IPC A61M, A61B, A61N & Keywords (gas+, line+, heart+, implant+, through+, plural) and like terms		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6132636 A (FREED et al.) 17 October 2000 Figures 3-5	1,2,3,5,7,14
X	WO 2001/083001 A1 (VASCA, INC.) 8 November 2001 Figure 1, Page 7 Lines 18-23	1, 2, 3, 5, 7, 11, 12, 13
A	US 5089017 A (YOUNG et al.) 18 February 1992 Figure 4, Page 3 Lines 11-20, Page 4 Lines 49-53	1
A	EP 0364799 B1 (DELCATH SYSTEMS INC.) 25 April 1990 Figure 1	1
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 2 February 2005		Date of mailing of the international search report 7 FEB 2005
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pet@ipaaustralia.gov.au Facsimile No. (02) 6283 3929		Authorized officer  MATTHEW FORWARD Telephone No: (02) 6283 2606

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 1999/002213 A1 (NEW YORK UNIVERSITY) 21 January 1999 Figure 1-2	1

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/AU2004/001485**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	2001083001	AU	61080/01	EP	1278562		
US	6132363	AU	15366/02	AU	95919/98	BR	9812700
		CA	2303818	EP	1019115	US	6487512
		US	6511412	US	6735532	US	2003074144
		WO	2002032478	WO	1999016481		
US	5089017	WO	1993010829				
EP	0364799	JP	2193676	US	5069662	US	5411479
WO	199902213	US	5921965				
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							

# PATENT COOPERATION TREATY

From the:  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 15 FEB 2005

WIPO PCT PCT

To:

SPRUSON & FERGUSON  
GPO Box 3898  
SYDNEY NSW 2001

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) 7 FEB 2005

Applicant's or agent's file reference  
652472C

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
**PCT/AU2004/001485**

International filing date (day/month/year)  
28 October 2004

Priority date (day/month/year)  
31 October 2003

International Patent Classification (IPC) or both national classification and IPC

Int. Cl. <sup>7</sup> A61M 39/00, A61M 1/10

Applicant

SUNSHINE HEART COMPANY PTY LTD et al

### 1. This opinion contains indications relating to the following items:

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> Box No. I | Basis of the opinion   |
| <input type="checkbox"/> Box No. II           | Priority   |
| <input type="checkbox"/> Box No. III          | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/> Box No. IV           | Lack of unity of invention   |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI           | Certain documents cited  |
| <input type="checkbox"/> Box No. VII          | Certain defects in the international application   |
| <input type="checkbox"/> Box No. VIII         | Certain observations on the international application  |

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU  
AUSTRALIAN PATENT OFFICE  
PO BOX 200, WODEN ACT 2606, AUSTRALIA  
E-mail address: pct@pausa.gov.au  
Facsimile No. (02) 6285 3929

Authorized Officer

**MATTHEW FORWARD**  
Telephone No. (02) 6283 2606

WRITTEN OPINION OF THE  
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Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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**Box No. V**      **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 4, 6, 8-10	YES
	Claims 1-3, 5, 7, 11-14	NO
Inventive step (IS)	Claims 4, 6, 8-10	YES
	Claims 1-3, 5, 7, 11-14	NO
Industrial applicability (IA)	Claims 1-14	YES
	Claims	NO

**2. Citations and explanations:**

The following documents have been identified in the International Search report as possible citations for use in an inventive step or novelty argument:

D1 US 6132363 (Freed et al.)

D2 WO 2001/083001 (Vasca, Inc.)

The present application is for a 2-part gas-line and the method of using it, where one part of the gas-line is implanted entirely under the skin and is accessed through the use of a connection fitting that forms the end of the gas-line. The second part is partly implanted and protrudes from the skin, being removably sealed to the connection fitting.

Document D1 discloses a cardiac assist device that is composed of a blood pump, an inflatable bladder and a percutaneous access device (PAD) and an external drive unit. The PAD provides the connection through which an external line can be connected after penetrating the skin. This citation is referenced in the specification on page 1 lines 11-19 as background art. It is submitted that the claims 1, 2, 3, 5, 7, 14 have been anticipated by this document and consequently lack novelty and inventive step.

Document D2 discloses a method and an apparatus for introducing or draining the body of fluid through use of multi-part tubing sets, whereby sets of tubes could be used in conjunction with the connection fitting located in the patient. It is submitted that the claims 1, 2, 3, 5, 7, 11, 12, 13 have been anticipated by this document and consequently lack novelty and inventive step.